AMENDMENTS TO THE DRAWINGS

The attached sheets of drawings includes changes to Figs. 5F, 16, 19 and 20 These sheets, which include Figs. 5F, 16, 19 and 20, replace the original sheets including Figs. 5F, 16, 19 and 20 . Annotated Sheets showing the changes are included with this amendment.

Attachment: Replacement Sheet(s)
Annotated Sheet Showing Changes

REMARKS

Claims 19-28 and 34-44 are pending. By this Amendment, the specification and Figs. 5F, 16, 19 and 20 are amended. Reconsideration and allowance are respectfully requested in view of the foregoing amendments and the following remarks.

Claims 19, 20, 22, 23, 27 and 34-42 were rejected under 35 U.S.C. §102(a) over Amarasinghe et al. (WO 02/45784). The rejection is respectfully traversed.

Although claim 24 is not identified on page 2, paragraph number 3, of the Office Action as being included in the rejection, as claim 24 is addressed on page 4 of the Office Action, Applicants' assume that claim 24 is included in the rejection. Similarly, although page 2, paragraph number 3 does not identify claims 43 and 44 as being rejected, as these claims are addressed on page 6 of the Office Action, Applicants' assume that they too are included in the rejection under 35 U.S.C. §102(a).

Claim 19 recites a mask assembly for application of non-invasive positive pressure ventilation to a patient comprising a frame including a main body having at least one aperture configured to receive a supply of breathable gas under pressure. The frame includes at least one selected frame portion provided to the main body. The at least one selected frame portion is adjustable relative to the main body. A cushion is provided to the frame. The cushion is structured to provide an interface with the patient. The at least one selected frame portion is engaged with the cushion so that the cushion is adjustable in accordance with a position of the at least one selected frame portion relative to the main body. The cushion, upon application of positive pressure, applies a force to the patient. The force is adjustable in accordance with 1) the position of the at least one selected frame portion relative to the main body for a given value of the positive pressure; and/or 2) variations in the positive pressure.

The standard of anticipation under 35 U.S.C. §102 is identity of invention. In other words, as stated in M.P.E.P. §2131, "the identical invention must be shown in as complete detail as is contained in the...claim." (Citing Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989)).

Amarasinghe et al. do not anticipate claim 19 because Amarasinghe et al. do not disclose or suggest, at least, at least one selected frame portion engaged with the cushion so that the cushion is adjustable in accordance with a position of the at least one selected frame portion relative to the main body of the frame.

The Office Action states on page 2, paragraph number 3, that the brace 12 of Amarasinghe et al., which the Examiner alleged corresponds to the at least one selected frame portion of claim 19, is engaged with the cushion 16 (by wrapping around the cushion as seen in Fig. 2).

Firstly, it is respectfully noted that Amarasinghe et al. do not disclose or suggest that the brace 12 engages the cushion 16. Amarasinghe et al. disclose on page 6, lines 1-15, that the brace 12 assumes a fixed predetermined position with respect to the mask shell 13, the existing mask shell headgear attachment points 17 serving as retaining formations for the brace 12. The brace 12 assumes a substantially constant position relative to the mask shell when the mask assembly is properly located on the user.

The brace 12 of Amarasinghe et al. is not wrapped around the cushion 16, as alleged by the Examiner. In fact, the brace head strap attachment points 15 of the brace 12 extend away from, and do not engage, the cushion 16 as shown, for example, in Figs. 3-5 of Amarasinghe et al.

Secondly, even assuming that the brace head strap attachment points 15 of the brace 12 did engage the mask cushion 16, which Applicants do not concede, such engagement would not adjust the cushion in accordance with a position of the brace 12 relative to the mask shell 13. As disclosed on page 6, lines 6-7, of Amarasinghe et al., the brace 12 assumes a fixed position with respect to the mask shell 13.

In response to the arguments filed August 14, 2008, the Examiner on page 8, paragraph number 8, of the Office Action, states that "a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim."

The Examiner then goes on from pages 8 through 9 of the Office Action and states in the instant case, "the brace (12) is a malleable wire that is engaged with a cushion (via strap and a shell) and the brace is easily maneuvered by hand and Amarasinghe specifically shows portions (15) of brace (12) wrapping around the cushion (16) in Fig. 2. Therefore, the brace (12) is structured to engage the cushion (16) via shell (13) and tightening of the straps; and the tightness of the cushion would inherently be adjusted via the straps connected to brace (12)."

Claim 19 does not recite an intended use of the at least one selected frame portion, nor does claim 19 recite that the at least one selected frame portion is structured to engage with the cushion, as alleged by the Examiner. Claim 19 recites that the at least one selected frame portion is engaged with the cushion.

Claim 19 also does not recite that the at least one selected frame portion is engaged with the cushion via, for example, a strap or a shell, of the mask assembly. Claim 19, again, recites that the at least one selected frame portion is engaged with the cushion, and not the other features

identified by the Examiner. The Examiner concedes the failure of Amarasinghe et al. to disclose or suggest this feature by improperly interpreting claim 19 to recite an intended use and/or improperly interpreting claim 19 to recite that the at least one selected frame portion is structured to engage the cushion, or engages the cushion "via" other elements of the mask assembly. Claim 19 does not recite either. Claim 19 recites that the selected frame portion is engaged with the cushion.

As also discussed above, Fig. 2 of Amarasinghe et al. does not disclose that the brace "wraps around" the cushion 16, nor does Fig. 2 show the brace 12 engaged with the cushion 16. In fact, as discussed above the remaining Figs. 3-5 of Amarasinghe et al. clearly show that the brace 12, and the brace headgear strap attachment points 15 of the brace 12, do not contact the cushion 16.

As Amarasinghe et al. do not disclose the identical invention recited in claim 19, the rejection fails to present a *prima facie* case of anticipation.

Claims 20, 22-24, 27 and 43 recite additional features and are allowable for the same reasons discussed above with respect to claim 19 and for the additional features recited therein.

Claim 20 recites that at least one headgear connector portion is provided to the at least one selected frame portion and the at least one selected frame portion is adapted to be movable in accordance with change in headgear strap tension to thereby adjust the force applied to the size of the patient's nose and/or face in use.

The Examiner, on page 3, lines 9-13, of the Office Action, alleges that the brace head strap attachment points 15 of the brace 12 of Amarasinghe et al. are adapted to be movable in accordance with a change in headgear strap tension and directs Applicants' attention to Fig. 2 of Amarasinghe et al. Applicants respectfully disagree.

As discussed above, Amarasinghe et al. disclose that the brace depicted in Fig. 2 assumes a substantially constant position relative to the mask shell when the mask assembly is properly located on the user. See page 6, lines 9-12, of Amarasinghe et al. In other words, Amarasinghe et al. clearly disclose that no portion of the brace 12, including the brace head strap attachment points 15, is adjusted relative to the mask shell 13 when the mask assembly is located on the user.

Claim 22 recites that the at least one selected frame portion includes a flexible member supporting the cushion. The Examiner states on page 3, lines 14-17, of the Office Action, that Amarasinghe et al. disclose that the brace head strap attachment points 15 "supports the cushion by wrapping around it when the straps are fitted around a user's head." The Examiner directs Applicants' attention to Fig. 2 of Amarasinghe et al.

As discussed above, Amarasinghe et al. do not disclose or suggest that the brace head strap attachment points 15 either wrap around the cushion 16 or engage the cushion 16. Furthermore, as also discussed above, Amarasinghe et al. disclose that the brace 12 assumes a substantially constant position relative to the mask shell. In other words, Amarasinghe et al. do not disclose or suggest that the brace head strap attachment points 15 wrap around the cushion when the straps are fitted around a user's head, as alleged by the Examiner.

Claim 23 recites that the main body and the at least one selected frame portion are provided as two separate parts that are coupled to one another. As discussed above, the brace 12 of Amarasinghe et al. does not correspond to the at least one selected frame portion of claim 23 and base claim 19 because the brace 12 of Amarasinghe et al. does not engage the cushion 16, as recited in base claim 19.

Claim 24 recites that the main body and the at least one selected frame portion are movable by a camming mechanism.

The Examiner states on page 4, lines 1-9, of the Office Action, that "there is no structural limitation added to this claim." The Examiner then goes on to state that it is his "position that the main body and the selected portion" of Amarasinghe et al. (i.e. the shell 13 and the brace 12) "are movable by a camming mechanism...[s]ince a cam is merely a projecting part of a rotating wheel or shaft that strikes a lever at one or more points on its circular path, if a cam were to contact a mask, or a package containing the mask, the main body and the selected portion would be movable by a camming mechanism." The Examiner then concludes that "[s]ince the camming mechanism is not part of the claimed apparatus, and the main body and the at least one selected frame portion" (i.e. the shell 13 and the brace 12) "are deemed to be movable by a camming mechanism, the apparatus disclosed by Amarasinghe et al. meets the claim."

The Examiner's determination that a camming mechanism is not part of the mask assembly of claim 14 is simply incorrect. Claim 24 plainly and clearly recites that the main body and the at least one selected frame portion are movable by a camming mechanism. It is also unclear how the Examiner can conclude that claim 24 does not require the prior art to disclose or suggest a camming mechanism, but then conclude that Amarasinghe et al. do disclose a camming mechanism and thus "meet the claim."

Applicants also respectfully note that the Examiner does not cite any portion of Amarasinghe et al. allegedly corresponding to a camming mechanism, as required by 37 C.F.R. §1.104(c)(2). Furthermore, the Examiner's determination that "if a cam were to contact the mask, or a package containing the mask, the main body and the selected portion would be movable by a camming mechanism," is nothing more than speculation on the part of the

Examiner. If Amarasinghe et al. actually disclosed the features recited in claim 24, Amarasinghe et al. would anticipate the claimed invention. However, as Amarasinghe et al. do not disclose or suggest the invention recited in claim 24, Amarasinghe et al. do not anticipate the claim.

Claim 27 recites that the at least one selected frame portion includes each lateral side of the frame which is made of a flexible material.

The Office Action on page 4, lines 10-12, alleges that Amarasinghe et al. disclose that the brace head strap attachment points 15 are made of a flexible material and directs Applicants' attention to page 7, lines 21-27, of Amarasinghe et al.

Amarasinghe et al. disclose that the brace 12 is constructed of mild steel wire butt-welded so as to assume a continuous form. The wire is bent to the appropriate configuration using standard wire bending techniques which may include automated bending by way of a suitably programmed wire bending machine.

It is respectfully submitted that Amarasinghe et al.'s disclosure of a brace 12 formed of bend steel wire is not a disclosure of at least one selected frame portion including each lateral side of a frame being made of a flexible material, as recited in claim 27. In fact, Amarasinghe et al. disclose on page 7, lines 18-20, that the brace 12 is relatively rigidly engaged with the mask shell 13.

Claim 34 recites a mask assembly for application of non-invasive positive pressure ventilation to a patient comprising, *inter alia*, a selected frame portion engaged with a cushion so that the cushion is adjustable in accordance with a position of the selected frame portion relative to a main body of the frame. Claim 34 further recites that the selected frame portion includes each lateral side of the frame and a selected frame portion as bendable to cause each lateral side of the frame to push against sides of the cushion.

As discussed above with respect to independent claim 19, Amarasinghe et al. do not disclose or suggest that the brace 12 engages the cushion 16. Furthermore, Amarasinghe et al. do not disclose or suggest that the brace 12 is bendable to cause lateral sides of the shell 13 to push against sides of the cushion 16. Accordingly, Amarasinghe et al. do not anticipate claim 34.

In response to Applicants' arguments that Amarasinghe et al. do not disclose a selected frame portion being bendable to cause each lateral side of the frame to push against the sides of the cushion, the Examiner responds on page 9, lines 13-15, of the Office Action, that Amarasinghe et al. disclose that the brace 12 is bendable and the brace 12 surrounds the body of the mask with lateral projections (i.e. the brace head strap attachment points 15) of the brace 12.

As discussed above, Amarasinghe et al. do not disclose that the brace 12 either wraps around the cushion 16 or engages the cushion 16. Furthermore, Amarasinghe et al. do not disclose or suggest that the brace 12 is bendable to cause lateral sides of the mask shell 13 to push against sides of the cushion 16. Amarasinghe et al. clearly disclose on page 6, lines 6-7, that the brace 12 assumes a fixed predetermined position with respect to the mask shell 13.

With respect to claim 35, the Examiner alleges on page 5, lines 4-6, of the Office Action, that the stabilizing portion 20 of Amarasinghe et al. supports the cushion 16. The Examiner directs Applicants' attention to page 7, lines 8-20, of Amarasinghe et al. It is respectfully noted, however, that Amarasinghe et al. do not disclose or suggest anything about the stabilizing portion 20 of the brace 12 supporting the cushion 16, as alleged by the Examiner.

With respect to claim 36, as Amarasinghe et al. do not disclose or suggest a flexible member supporting the cushion, Amarasinghe et al. cannot anticipate or render obvious the claim.

With respect to claim 37, as the shell 13 and the brace 12 of Amarasinghe et al. do not correspond to the main body and the selected frame portion, the claim is neither anticipated nor rendered obvious by the reference.

Claim 38 recites that the selected frame portion includes each lateral side of the frame which is made of a flexible material. As discussed above with respect to, for example, claim 27, the wire brace 12 of Amarasinghe et al. is not made of a flexible material. As also discussed above, the brace head strap attachment points 15 of Amarasinghe et al. are not bendable or flexible as Amarasinghe et al. disclose on page 7, lines 18-20, that the brace 12 is relatively rigidly engaged with the mask shell 13 and disclose on page 6, lines 6-7, that the brace 12 assumes a fixed predetermined position with respect to the mask shell 13.

With respect to claim 40, the brace head strap attachment points 15 of Amarasinghe et al. do not correspond to the side wing portions as alleged by the Examiner because they are not movable relative to the mask shell 13 to adjust sides of the cushion 16.

Reconsideration and withdrawal of the rejection under 35 U.S.C. §102(a) over Amarasinghe et al. are respectfully requested.

Claim 21 was rejected under 35 U.S.C. §103(a) over Amarasinghe et al. in view of Gradon et al. (U.S. Patent Application Publication 2003/0089373 A1) and claims 25, 26 and 28 were rejected under 35 U.S.C. §103(a) over Amarasinghe et al. in view of Hellings et al. (U.S. Patent 5,975,079). The rejections are respectfully traversed.

Both Gradon et al. and Hellings et al. fail to cure the deficiencies of Amarasinghe et al. with respect to the claims discussed above and even assuming it would have been obvious to combine the references, which Applicants do not concede, the combination would not result in any of the claimed inventions.

Reconsideration and withdrawal of the rejections under 35 U.S.C. §103(a) are respectfully requested.

In view of the above amendments and remarks, Applicants respectfully submit that all claims are patentable and that the entire application is in condition for allowance.

Should the Examiner believe that anything further is desirable to place the application in better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: /John P. Darling/
John P. Darling
Reg. No. 44,482

JPD:tlm
901 North Glebe Road, 11th Floor
Arlington, VA 22203-1808
Telephone: (703) 816-4000
Facsimile: (703) 816-4100